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Manufacturer's Recall of Rapid Cartridge Assay Kits on the Basis of False-Positive *Cryptosporidium* Antigen Tests — Colorado, 2004

The Colorado Department of Public Health and Environment (CDPHE) has determined that a fourfold increase in the number of reported cryptosporidiosis cases in Colorado during January–February 2004 might be attributed primarily to false-positive test results. Since January 1, 2004, a total of 13 in-state cases and one out-of-state case were reported to CDPHE. During the previous 7 years, an average of three cases were reported during January–February. In eight of 14 patients, rapid testing was performed by using the ImmunoCard STAT!® *Cryptosporidium/Giardia* Rapid Assay (Meridian Bioscience, Inc., Cincinnati, Ohio). This assay is a solid-phase qualitative immunochromatographic assay designated to detect and distinguish between *Giardia intestinalis* (*lamblia*) and *Cryptosporidium parvum* in aqueous extracts of human fecal specimens. Seven of these samples were tested by using lot no. 081093 (expires August 11, 2004). Of the seven samples that tested positive initially for *Cryptosporidium* with this lot number, four were retested by using other, more specific tests. One patient sample was positive by direct microscopy, one was negative by direct microscopy, and two were negative by direct fluorescent-antibody testing, suggesting that results for three of the four samples were false positive. The results of testing for *Giardia intestinalis* (*lamblia*) with these kits are unclear. Several other states have noted increases in the number of reported cryptosporidiosis cases that also might be associated with use of these rapid assays.

Meridian Bioscience, Inc., has voluntarily recalled two lots (lot no. 081077 [expires July 11, 2004] and lot no. 081093) from laboratories. CDC recommends reconfirmation of positive test results obtained with ImmunoCard STAT!® rapid assays from these lots.

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